

Notice of Allowability

Application No.

09/925,236

Examiner

Nashaat T. Nashed, Ph. D.

Applicant(s)

KHOSLA ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 1/18/05.
2. ☒ The allowed claim(s) is/are 96-101.
3. ☒ The drawings filed on 19 February 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 10/04/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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The application has been amended as requested in the communication filed January 18, 2005. Accordingly, claims 104-115 have been canceled, and claim 96 has been amended.

Claims 96-101 are pending and under consideration.

The terminal disclaimer filed on January 18, 2005 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of any of U. S. patents 6,399,382; 5,672,491, and 6,022,731 has been reviewed and is accepted. The terminal disclaimer has been recorded.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kate H. Murashige on February 25, 2005.

The application has been amended as follows:

Amend claim 96 as shown bellow:

Claim 96 A method to prepare actinomycete cells containing at least one nucleic acid molecule, wherein said molecule comprises at least one module that encodes a modular polyketide synthase (PKS) functional in catalyzing the synthesis of a polyketide, said module comprising at least one nucleotide sequence which encodes a PKS acyl transferase (AT) activity; at least one nucleotide sequence which encodes a PKS ketoacyl carrier protein synthase (KS) activity; and at least one nucleotide sequence which encodes a PKS acyl carrier protein (ACP) activity; said module operatively linked to a control sequence, whereby a functional modular PKS is produced in said cells, with the proviso that said module or said control sequence is heterologous to host cells, said method comprising introducing said nucleic acid molecule into actinomycete host cells that is natively produce polyketide.

Claims 96-101 are allowed.

The following is an examiner's statement of reasons for allowance: The specification teaches and enables a method transforming an actinomycete host cells with a heterologous gene encoding modular polyketide synthase (PKS) as will as the expression of said heterologus gene in said host cells. The examiner agrees with the

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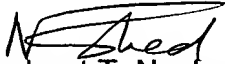
applicants that US patents 5,824,513 ('513) and 6,004,787 ('787) do not teach the heterologous expression of PKS in a host cell. The claim is directed to a method for making modifies polyketide by (1) isolating a PKS gene cluster from a cell; (2) identifying enzymatic activity; (3) modify the gene cluster; and (4) replace the original gene cluster with the modified gene cluster by homologues recombination, taught in the specification of '787 patent. Since the modified gene cluster was originated from the same organism as that of the host cell, the examiner considers that a homologues expression. Thus, the '787 patent does not anticipate or suggest the claimed invention. Since the claims are free of the prior art, the claims are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Nashaat T. Nashed, Ph. D.
Primary Examiner
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